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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,110	10/30/2003	Jerome B. Zeldis	9516-083-999	1866

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EXAMINER	
FAY, ZOHREH A	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
11/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/699,110	ZELDIS, JEROME B.	
	Examiner	Art Unit	
	ZOHREH A. FAY	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,18 and 19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 18-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 15, 2008 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al. (U.S. Patent 6,020,358) in view of Tobinick (U.S. Patent 6,428,787) and D'Amato (U.S. Patent 6,235,756).

Muller et al. teach the use of the claimed compounds as TNF alpha reducing compounds. See the abstract, column 1, lines 1-10 and columns 5-8. Tobinick teaches the use of TNF alpha blockers or antagonists for the treatment of macular disorders, such as macular degeneration. See Column 1, lines 10-25, column 2 lines 25-39 and claim 6. D'Amato teaches the use of the claimed secondary components, such as thalidomide for the treatment of angiogenic disorders, such as macular degeneration. See the abstract and column 5, lines 10-30. The primary reference differs from the claimed invention in the use of the claimed compound for the treatment of macular degeneration, and the addition of the secondary angiogenic compounds, such as thalidomide. It would have been obvious to a person skilled in the art to use the claimed compound individually or in combination with a secondary angiogenic compound for the treatment of macular degeneration, motivated by the teachings of Tobinick and D'Amato, which teach the use of TNF alpha inhibitors, and also the use of the secondary components, such as thalidomide for the treatment of macular degeneration.

One skilled in the art would have been motivated to combine the teachings of the above reference, since one relates to the use of the claimed compound having TNF

alpha reducing effect, the other relates to the compounds having TNF inhibitory effect for the treatment of macular degeneration and the third reference teaches the use of the claimed secondary components, such as thalidomide for the treatment of macular degeneration as old. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 1-7, 18 and 19 are properly rejected under 35 U.S.C. 103.

Applicant's arguments and declaration have been carefully considered, but are not deemed to be persuasive. Applicant in his declaration uses 5, 10 and 25 mg/Kg of the claimed compound orally in comparison with 5 ul Lucentis intravitreally, and demonstrates the superior effect of the claimed compound on choroidal neovascularization. The data in the specification are not deemed to be persuasive. Such data are not commensurate in scope with the claimed language. Such data are done at 3 concentrations of the claimed compound by oral administration; however the claimed language is not limited to any concentrations or oral administration. Furthermore, the comparative data are not done at the equal concentration for the claimed compound and Lucentis. Finally, the data show the effect of the claimed compound on neovascularization; however the claims of the instant application are drawn to a method of treating macular degeneration. No correlation has been established between the treatment of choroidal neovascularization and the treatment of macular degeneration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZOHREH A. FAY whose telephone number is (571)272-0573. The examiner can normally be reached on Monday to Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ZF
/Zohreh A Fay/
Primary Examiner, Art Unit 1612